



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

October 27, 1999

via Federal Express

MQSA Facility ID: 113795
Inspection ID: 1137950008
FDA Reference #: 2951650

George M. Takushi, M.D.
Chief Radiologist
George M. Takushi, M.D., Inc.
2525 South King Street, Suite 304
Honolulu, Hawaii 96826

Dear Dr. Takushi,

We are writing to you because on August 6, 1999, your facility was inspected by a representative of the State of Hawaii, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and level 2 findings at your facility:

Level 1: Processor QC records were missing twenty-five out of twenty-five days (100%) of operation in month September 1998, for processor [REDACTED] located in room #1. {21CFR§900.12(e)(1)}

Level 1: Processor QC records were missing forty-two consecutive days for processor [REDACTED] located in room #1. {21CFR§900.12(e)(1)}

Level 2: The processing speed (using the S.T.E.P. procedure) is seventy-seven, which is greater than or equal to sixty-five, but less than eighty for standard processing for processor [REDACTED] located in room #1. {21CFR§900.12(e)(1)}

Level 2: The measured optical density attributable to darkroom fog is equal to 0.16, which exceeds the limit of 0.05, for darkroom #1. {21CFR§900.12(e)(4)(i)}

Level 2: Mammograms were processed in processor [REDACTED] located in room #1, when it was out of limits on two days. {21CFR§900.12(e)(1)}

Level 2: The radiologic technologist did not meet the requirement of having specific mammography training: [REDACTED] {21CFR§900.12(a)(2)(ii)}

Level 2: Ten out of ten random reports reviewed did not contain an assessment category. {21CFR§900.12(c)(1)(iv)}

Additionally, the inspection revealed the following level 3 finding at your facility:

Level 3: The darkroom fog QC records were not done at the required frequency, which is at least semiannually, for darkroom #1. {21CFR§900.12(e)(4)(i)}

The specific problems noted above appeared on your initial MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. Since the two Level 1 noncompliances, listed in this letter and in your initial inspection report, occurred prior to the implementation of the Final Regulations on April 28, 1999, your MQSA Facility Inspection Report will be revised to classify those Level 1 noncompliances as Level 2. We are making this change, since the FDA had different criteria for Level 1 findings that occurred prior to April 28, 1999. However, after reviewing the overall findings of the inspection, we decided that the severity of conditions warrant this notification.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken or plan to take to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

John M. Doucette, MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
510-337-6793 (tel)
510-337-6702 (fax)

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. John M. Doucette at 510-337-6793.

Sincerely yours,

Charles D. Moss
Acting District Director
for Patricia C. Ziobro
District Director
San Francisco District Office